

### **REMARKS**

In the non-final Office Action pending claims 1, and 3-15 stand rejected and claims 16-20 stand allowed.

Herewith Applicants amend independent claims 1 and 12, cancel no claims, and add no new claims.

Applicants respectfully request entry and favorable consideration of the amendments tendered herewith.

Applicants respectfully suggest that upon entry of the amendments to independent claims 1 and 12 herewith presented the application will be in condition for allowance. Applicants aver that the amendments were not earliest presented due to inadvertent oversight, and illustrated by the fact that Applicants argued (in the remarks section of the prior amendment) - and as pointed out by the Examiner at paragraph 2 of the final Office Action - along the lines of said amendments.

Applicants furthermore assert that the amendments presented herewith do not introduce New Matter or raise any new or additional issues requiring consideration of searching of art not now before the Examiner.

#### **Rejections under 35 U.S.C. §102**

**Claims 1, 5, 6, 8-12, 14, and 15 are rejected as allegedly anticipated under 35 U.S.C. §102(e) by the '806 published U.S. patent application to Hunter et al. (Hunter).**

Applicants respectfully traverse the rejections.

For the rejections to stand, *each and every claimed element* must be present in a single reference.

Applicants respectfully point out that Hunter is devoid of any teaching regarding navigation of a distal portion of a medical electrical lead through a portion of a coronary sinus based on differing (i.e., increased) temperature of

blood (i.e., exploiting the fact that a temperature variation exists between blood present within the right atrium and blood exiting the coronary sinus).

**Rejections under 35 U.S.C. §103**

**Claims 3 and 4 are rejected as allegedly unpatentable over Hunter in view of the '148 patent to Lesh et al. (Lesh).**

According to the Examiner, Hunter allegedly discloses the claimed invention *except for* at least a lack of disclosure regarding that the temperature sensors could be a thermistor or thermocouple.

The Examiner concluded, however, that it would have been obvious to one of ordinary skill in the art at the time the invention was made to use "this method" since it is used for other cardiac anatomy and as such would be applicable for use in the right atrium and coronary sinus. Applicants respectfully point out that Hunter and Lesh are devoid of any teaching regarding a temperature variation existing between blood present within the right atrium and blood exiting the coronary sinus and using said variation to navigate around the anatomy of the right atrium.

Applicants repeat the foregoing information about Hunter2 as set forth above and note furthermore that Lesh is also devoid of disclosure regarding insertion of a chronically implanted medical electrical lead.

Indeed, Lesh deals with **ablation** of myocardial tissue and not with implantation of pacing leads and thus teaches away from the present invention.

In point of fact, Lesh specifically claims ablation; to wit:

1. A method for ablation of arrhythmogenic cardiac tissue comprising:
  - selecting a catheter comprising:
    - an elongated flexible body having a proximal end and a distal end,
    - an ultrasound assembly having a transducer located at the distal end of the body,
  - and a tissue ablation means;
  - introducing the distal end of the catheter into a cardiac chamber comprising the arrhythmogenic cardiac tissue to be ablated;
  - using the ultrasound assembly to position the tissue ablation means within an effective range of the arrhythmogenic cardiac tissue to be ablated; and
  - activating the tissue ablation means.

Also, the Abstract of Lesh further emphasizes its focus versus the present invention wherein temperature-based surgical navigation is the focus.

**Abstract**

Method and apparatus for ablation of cardiac tissue includes a catheter (2, 60) having an elongated flexible body (6, 64), a tissue characterization assembly including a transducer (34) at the distal end (16) of the body and a tissue ablation assembly having a tissue ablation tip (32) at the distal end of the body. The tissue ablation tip is positioned adjacent the tissue to be ablated using the visualization assembly and then activated.

Thus, it can be readily appreciated that one of skill in the art would not look to Lesh and thus, Lesh is not properly combined with Hunter and the ground of rejection should be withdrawn.

**Claims 7 and 13 are rejected as allegedly being unpatentable over Hunter in view of the '703 patent to Zanelli et al. (Zanelli).**

The Examiner asserts that Hunter discloses the applicant's basic invention except for an output signal that is audible in nature.

Applicants assert that the claims as amended are not rendered obvious by the combination of Hunter and Zanelli and that the proposed combination therefore fails to reach the minimum threshold for a *prima facie* obviousness rejection. That is, the references do include neither a suggestion nor a motivation to combine, and if in fact they were combined they would not produce the claimed invention.

**Conclusion**

Applicants submit that the pending claims are now in condition for allowance and request that a notice of allowance be issued in due course.

If there are any formal matters remaining after this response, the Examiner is requested to telephone the undersigned attorney to attend to these matters.

Respectfully submitted,

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